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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/399,083 09/17/99 CALDERWOOD

D BBC-043PA2

EXAMINER

HM12/0702

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ART UNIT

PAPER NUMBER

1624

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07/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/399,083

Applicant(s)

Calderwood et al.

Examiner

Deepak Ra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on May 7, 2001

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-8 and 10-48 ☒ are pending in the application.

4a) Of the above, claim(s) 11-45 and 48 ☒ are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-8, 10, 46, and 47 ☒ are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other: _____

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DETAILED ACTION

Claims 1-48 are pending in this application.

Election/Restriction

Applicant's election with traverse of Group I, claims 1-8, 10-11 and 46-48 in Paper No. 20 is acknowledged. The traversal is on the ground(s) that the groups share a common feature, compounds of claim 1. This is not found persuasive because as explained in the previous office action, distinct processes of use are claimed for the claimed products. Further, the only common feature in compounds of claim 1 is the 4-amino-pyrrolo[2,3-d]pyrimidine, which products are known to be used in processes different from the instant inventions of Groups II-III, e.g., in therapeutic methods related to endothelin receptor activity (see US'469). See MPEP § 806.05(h) according to which only one of the above conditions need to be satisfied for a restriction between process of use and products. In the instant case both conditions are met and applicants have not provided any evidence to the contrary.

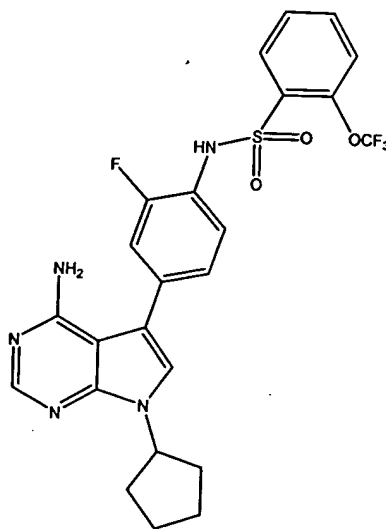
The requirement is still deemed proper and is therefore made FINAL.

Claims 12-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 20.

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Applicant's election of the species N-(4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimidin-5-yl)-2-fluorophenyl)-2-(trifluoromethoxy)-1-benzenesulfonamide is acknowledged.

The species is depicted below for convenience:



The species represents a compound of structural formula of claim 1 wherein:

A is a 2-fluorophenyl;

L is -NH-SO₂-;

j is 0;

R₃ is 2-trifluoromethoxyphenyl;

R₂ is H; and

R₁ is cyclopentyl.

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As per the guidelines provided in MPEP § 803.02, upon examination if prior art is found for the elected species, the examination will be limited to the elected species. Accordingly, the Markush-type claims are examined to the extent readable on the elected species.

Content of MPEP § 803.02 is provided here for convenience:

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the non-elected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the merits on the elected claims would be final. On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. **The prior art search, however, will not be extended unnecessarily to cover all nonelected species.** Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

As the elected species was not found in the prior art, the search was expanded to compounds of the structural formula of claim 1, wherein A is a substituted phenyl, L is -NH-SO₂-, j is 0, R₃ is t-butyl substituted phenyl, R₂ is H and R₁ is cyclopentyl, and art was found. Claims 11 and 48 are additionally withdrawn from consideration as being drawn to nonelected inventions (see MPEP § 803.02). All other definitions of the variables and the species are withdrawn from further consideration.

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Priority

It is acknowledged that the instant application claims benefit from U.S. Provisional Application No. 60/100,834 filed September 18, 1998 and is a CIP of 09/042,702 filed March 17, 1998 (which claims benefit of Provisional application 60/040,836 filed March 19, 1997). It is noted however, that the instant claims are not entitled for priority of the effective filing date of S.No. 09/042,702 because the instantly claimed invention is not fully supported in the prior application, see the definitions of ring A, L, etc. wherein several groups are not disclosed in the previous application. For example, the parent application defines the substituent at the 5-position of the 4-amino-pyrrolo[2,3-d]pyrimidine to be phenyl substituted with AR₅ wherein A and R₅ are different in scope compared to the instantly claimed -L-(CH₂)_j-R₃. Therefore, the effective filing date for the instant claims is September 18, 1998. See MPEP § 706.02.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 10 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. In claim 1, several of the substituents recited for Ring A on page 3, lines 9-13 are confusing and unclear. Particularly the terms "alkylthio ether", "alkylsulfoxide",

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“alkylsulfone”, “arylthio ether”, “arylsulfoxide”, “arylsulfone”, “aliphatic ether”, “aromatic ether” all represent compounds and not substituent groups. Conventionally the term “ether” is known to represent R-O-R’ wherein R and R’ represent same or different groups. Therefore, the instant recitation of ‘aliphatic ether’ appears to represent groups such as alkoxyalkyl; and ‘aromatic ether’ represents aryloxyaryl, etc. Also, substituent groups having SO and SO₂ are generally recited as ‘sulfinyl’ and ‘sulfonyl’ respectively. The instant recitations in the claims are unconventional for substituent groups.

2. Claim 6 recites the limitation "OCF₃" and OCH₃" in lines 2-3, as the substituents on ring A. There is insufficient antecedent basis for this limitation in claim 1 on which claim 6 is dependent (through claim 5). Claim 1 does not define alkoxy or haloalkoxy as substituents on ring A.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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Claims 1-8, 10 and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Calderwood et al., U.S. Patent No. 6,001,839. The instant claims read on the compounds of the reference, see the reference compounds in col. 10, lines 13-14 and lines 26-27.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Calderwood et al., WO 98/41525. The reference teaches a generic group of compounds which embraces applicant's instantly claimed compounds. See formula I in page 2 wherein R₃ is represented by formula (a) wherein the phenyl ring of formula (a) is optionally further substituted (see page 3, lines 6-9); A is

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NHSO₂ (page 3, line 10) and R₅ is optionally substituted phenyl. The reference further discloses several species that fall within the above genus, see pages 10-14, particularly page 14, lines 9-14 and 22-23. The compounds are taught to be useful as pharmaceutical therapeutic agents having protein kinase inhibition activity, see the entire document. The claims differ from the reference by reciting specific species of the reference genus. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as pharmaceutical therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-8, 10 and 47 are rejected under the judicially created doctrine of double patenting over claims 1-24 of U. S. Patent No. 6,001,839 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The reference patent also claims an invention that is identical to the instantly claimed invention, see formula I in col. 37 and further, the specifically claimed compounds in col. 42, lines 36-37 and 49-50.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

2. Claims 1-8, 10 and 47 are provisionally rejected under the judicially created doctrine of double patenting over claim of copending Application No. 09/381,036. This is a provisional double patenting rejection since the conflicting claims have not yet been patented. The reasons are same as provided above for US'839. (S.No. 09/381,036 is a national stage application of PCT/EP98/01357 which claims priority from U.S. Provisional Application 60/040,836).

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3. Claim 46 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,001,839. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is no patentable distinction. Many of the instantly claimed compounds (e.g., the second species in claim 46) are encompassed by the reference genus. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole.

4. Claim 46 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim of copending Application No. 09/381,036. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed compounds are generically embraced by the reference claims. (See reasons provided in #3).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The copending application S.No. 09/381,036 cited in the Information Disclosure Statement filed on February 15, 2001 is considered.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can

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normally be reached on Tuesday-Friday from 6:30am to 5:00pm. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'Deepak Rao', is written over the printed name.

Deepak Rao
June 29, 2001